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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,904	07/29/2008	Nels J. Lauritzen	ASC 0002-US1	1251

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EXAMINER	
LIEB, JEANETTE M	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
11/09/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,904	LAURITZEN, NELS J.	
	Examiner	Art Unit	
	JEANETTE LIEB	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 September 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *21-35* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *21-35* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/26/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction Requirement

Applicant's election of Group II, claims 21-35 without traverse in applicant's response on 09/14/2011 is acknowledged. Claims 21-25 are pending. Applicants further elected the species, caudal tendon, for claims 23, 24, 28 and 32, an artificial dura for claims 33-35, and skin for claim 34. The elected invention reads on claims 21-35. An office action on the merits follows.

Claims 1-20 are withdrawn as being the non-elected invention. Claims 21-35, which read on the elected invention and species, were searched and an office action on the merits follows.

Claim Rejections - 35 USC § 102(b)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless-

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 21-24, 27 and 28 are rejected under 35 U.S.C. 102 (b) as being anticipated by Shadwick et. al. (*Structure and Function of tuna tail tendons*, COMPARATIVE BIOCHEMISTRY AND PHYSIOLOGY PART A (133) 1109-1125, 2002).

Shadwick et. al. teach that the collagen heterotrimer of the tuna caudal tendon is typical of vertebrate type I collagen, having two of the same alpha 1 (I) components and one different

alpha 2 (I) component making up the third link in the trimer (See Abstract). This reference further teaches that the removal of tendon material from *T. Albacores* by first determining the tendon water and collagen content through an amino acid analysis of the collagen amino acid content in the sample (p. 1112, Col. 1). This reference then teaches the purification and extraction of tendon collagen chopping, solubilizing, adding NaCl and acetic acid and reprecipitating the insoluble residue with NaCl (p. 1112, Col. 1).

This meets the limitations of claims 21-24, 27, and 28 by isolating and recovering collagen from a marine animal's caudal tendon. As to claims 22-24, the collagen is derived from the caudal tendon of a *T. Albacoris*, or Tuna, because the method is the same and the source is the same, the characteristics of the collagen product are inherent properties of the product. For example, the mole percent of each amino acid of claim 22 and the purity of claim 26, would be inherent based on the method and product. See MPEP 2112.01:

> Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best,* 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada,* 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best,* 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (Claims were directed to a titanium alloy containing 0.2-0.4% Mo and 0.6-0.9% Ni having corrosion resistance. A Russian article disclosed a titanium alloy containing 0.25% Mo and 0.75% Ni but was silent as to corrosion resistance. The Federal Circuit held that the claim was anticipated because the percentages of Mo and Ni were squarely within the claimed ranges. The court went on to say that it was immaterial what properties the alloys had or who discovered the properties because the composition is the same and thus must necessarily exhibit the properties).

Thus, the claims are anticipated by the prior art.

2. Claims 25, 26, 29-31 and 33-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Luck et. al. (US 4,233,360).

Luck et. al. teaches that collagen fibers generally consist of three polypeptide chains wound together in a triple helical formulation , and that two of the chains are identical, while the third is different based on their amino acid compositions (Col. 2, lines 50-63). This reference also teaches a method of obtaining collagen from a tendon source dispersing the collagen in an acid formulation, disposing it to active enzymatic treatment, to cleave the telopeptides and produce atelopeptide collagen (Col. 5, lines 5-27). This reference further teaches treatment by separations, precipitations, dialysis and treating the solution with an alkaline product such as sodium hydroxide to inactivate the enzyme (Col. 5, line 49-67). Finally, the reference teaches precipitation the collagen product as part of the purification process (Col. 6, lines 4-15).

This reference meets all of the limitations of claims 25-27, 29-31 and 33-35 because they are not drawn to collagen from a marine animal source, but to all of the active method steps of adding an enzyme, inactivating and washing the enzyme, alkalinizing and precipitating the collagen product from any tendon source. Further, the purity and chain structure of the collagen (Claims 26 and 27) have no bearing on the method employed to collect collagen products from the same source, a caudal tendon. As to claims 33-35, the added limitations have no bearing on the methods claims because they are drawn to a method of incorporating collagen into additional embodiments, not a method of obtaining a collagen product.

Thus, the claims are anticipated by the prior art.

Claim Rejections - 35 USC § 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 21-35 are rejected under 35 USC 103(a) as being unpatentable over Luck et. al. in view of Shadwick et. al.

The teachings of Luck et. al. have each been described supra.

The difference between Shadwick and the instant claims is that Shadwick does not specifically teach Marine animal collagen, or more specifically the caudal tendon of a Tuna used in the method steps of claim 29 (adding enzyme, washing the enzyme, alkalinizing, and precipitating the collagen).

In addition to the aforementioned teachings of Shadwick et. al., this reference also teaches that tuna caudal tendons link myotomal muscle directly to caudal fin rays and serve to transfer muscle power to the hydrofoil-like tail during swimming (See Abstract). This reference further teaches that the robust collagenous tendons of the tuna caudal tail have structural and mechanical similarity to tendons found in other vertebrates, such as the leg tendons of terrestrial mammals (See Abstract). As discussed above, Shadwick et. al. also teach that the collagen heterotrimer of the tuna caudal tendon is typical of vertebrate type I collagen, having two of the same alpha 1 (I) components and one different alpha 2 (I) component making up the third link in the trimer (See Abstract; See page 1121, Fig. 10). This reference teaches that the structural makeup of two alpha 1(I) chains and one alpha 2(I) chain are predominant in tendons as well as the bone and skin of most vertebrates (p. 1121, Col. 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used tuna caudal tendon as the source of collagen because Shadwick et. al. teach that tuna caudal tendons have functional and mechanical similarity to terrestrial mammal tendons and the structural makeup of the collagen in Shadwick is same as the structure of type I collagen taught by Luck. One would have been motivated to use the tuna caudal tendon in the methods of both Shadwick (as anticipated by the reference) and the methods of Luck et.al. because of the structural and mechanical similarities of the collagen in mammals and tuna caudal tendons.

There is a reasonable expectation of success that the tuna caudal tendon with be as effective a source of collagen as the mammal caudal tendons in the methods described by Luck et. al.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEANETTE LIEB whose telephone number is (571)270-3490. The examiner can normally be reached on 8:30am -5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JEANETTE LIEB/
Examiner, Art Unit 1654

/Anish Gupta/

Primary Examiner, Art Unit 1654